Toshiba America Medical Systems, Inc.
510(k) Pre-market Notification; Colon View CSCV-001A

K090220

510(k) Summary

FEB 11 2009

Date:	October 24, 2008
Submitter's Name:	Toshiba Medical System Corporation (TMSC)
Submitter's Address:	1385 Shimoishigami, Otawara-shi, Tochigi-ken, Japan, 324-8550
Submitter's Contact:	Paul Biggins, Director Regulatory Affairs Toshiba America Medical Systems, Inc.(TAMS) 2441 Michelle Drive Tustin, CA 92780 T: (714)730-5000 F: (714) 730-1310
Establishment Registration Number:	TMSC: 9614698 TAMS: 2020563
Device Proprietary Name:	Colon View CSCV-001A
Common Name:	CT Colonography Software Scanner, Computed Tomography, X-Ray [Fed. Reg. No. 892.1750, Pro. Code: 90JAK]
Regulatory Class:	II (per 21 CFR 892.1750)
Performance Standard:	21 CFR Subchapter J, Federal Diagnostic X-ray Equipment Standard
Predicate Device(s):	GE CT Colonography II [k041270] GE Ct Colonography [k023943] Siemens syngo Colonography [k042605] Siemens syngo Colonography [k030982]
Reason For Submission	New software package

Description of this Device:

Colon View is a post processing software package that allows for the review, annotation and reporting of 2D, 3D and MPR images, obtained from volume datasets, of colon images.

Summary of Intended Uses:

This application software is an image analysis package that allows for the visualization of the colon using volume datasets that provide 2D, 3D and MPR images. When employed by a qualified physician, this package can be used to observe polyps, masses and other lesions of the colon. Upon observation of the potential lesion the physician can mark and categorize the observed lesion.

This package also allows for the generation of reports that can be exported to DICOM based PACS systems for the continued tracking of changes in the colon.

Technological Characteristics:
This device is a post processing software package that enhances currently available #D image review software. The software does not control the CT scanner, thus has no effect on radiation dose, but allows for the processing of image data for the colon.

Safety and Effectiveness Concerns:
This device is designed and manufactured under the Quality System Regulations as outlined in 21 CFR § 820.

Substantial Equivalence:
This device is a software package that contains similar features of the predicate devices that are commercially available at this time.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Toshiba America Medical Systems, Inc.
% Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services LLC
1394 25th Street NW
BUFFALO MN 55313

FEB 11 2009

Re: K090220
Trade/Device Name: Colon View CSCV-001A
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: JAK
Dated: January 28, 2008
Received: January 29, 2008

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801; good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding os substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxx	(Gastroenterology/Renal/Urology)	(240) 276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	(240) 276-0115
21 CFR 892.xxx	(Radiology)	(240) 276-0120
Other		(240) 276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufactures, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry.suppot/index.html.

Sincerely yours,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K090220

Device Name: Colon View CSCV-001A

Indications for Use:

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Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K090220